CASE 33397-US-PCT IAP15 Rec'd PCT/PTO C 6 APR 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

PAUL E. GOSS

INTERNATIONAL APPLICATION NO: PCT/EP2004/011303

FILED: 8 OCTOBER 2004 U.S. APPLICATION NO: 35 USC §371 DATE:

FOR: BREAST CANCER TREATMENT REGIMEN

MS: Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The listed references were cited in the international stage search report. Since these references are of record in the instant PCT application PCT/EP2004/011303, copies are not enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

IAP15 Rec'd PCT/PTO \hat{C} 6 APR 2006

Respectfully submitted,

Lydia T. McNally

Reg. No. 36,214

Attorney for Applicant

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7898

Date: april 6,2006

FORM PTO-1449 (REV. 7-85)

AS

AT

EXAMINER

(2002)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

IAP15 Rec'd PCT/PTO C 6 APR 2006

ATTY. DOCKET NO.
33397-US-PCT

10/574744

ATTY. DOCKET NO. 33397-US-PCT APPLICATION NO. Not Yet Known APPLICANT Paul E. GOSS FILING DATE Herewith

Group

U.S. PATENT DOCUMENTS

| XAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILI | NG DATE |
|--------------------|----|---|--------|--|--------------|----------|-------------|--------------|
| | AA | | | | | | | |
| | AB | | | | | | | |
| | AC | | | | | | | |
| | AD | | | | | | | |
| | AE | | | | | | | |
| - | AF | , | | | | | | |
| | AG | | | | | | | |
| | АН | | | | | | | |
| | Al | | | | | | | |
| | AJ | | | | | | | |
| | AK | | | | | | | |
| | AL | • | | | | | | |
| | | | FOREIG | ON PATENT DOCUMENTS | | | | |
| | | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRAN YES | SLATIO NO |
| | AM | | | | | | | |
| | AN | | | | | | | |
| | AO | | | | | | | |
| | AP | | | | | | | |
| | AQ | | | | | | | |
| | | OTHER DOC | UMENTS | (Including Author, Title, Date, Pertin | ent pages, E | tc.) | | |
| | AR | Goss et al., "A Randomised Trial of Letrozole in Postmenopausal Women after Five Years of Tamixofen Therapy for Early-Stage Breast Cancer," New England Journal of Medicine, Vol. 349, No. 19, pp. 1793-1802 (2003) | | | | | | |
| | 1 | | | - clinical trials strategies involvi | | ! | " laur | 1 -6 |

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

Goss et al., "Tamoxifen Resistant and Refactory Breast Cancer," Drugs, Vol. 62, No. 2, pp. 957-966

DATE CONSIDERED

Steroid Biochemistry and Molecular Biology, Vol. 86, pp. 487-493 (2003)

FORM PTO-1449 (REV. 7-85)

EXAMINER

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. 33397-US-PCT APPLICATION NO. Not Yet Known APPLICANT Paul E. GOSS FILING DATE

Herewith

IAP15 Rec'd PCT/PTO 66 APR 2006 ATTY. DOCKET NO. 10/574744

Group

EXAMINER INITIAL OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.) Jones, "Antiaromatase Agents: Evolving Role in Adjuvant Therapy," Clinical Breast Cancer, Vol. 3, No. 1, pp. 33-42 (2002) DA Goss, "The Evolving Role of Aromatase Inhibitors in the Adjuvant Breast Cancer Setting," American Journal of Cancer, Vol. 2, No. 1, pp. 13-15 (2003) DB Ingle et al., "Evaluation of Tamoxifen plus Letrozole with Assessment of Pharmacokinetic Interaction in Postmenopausal Women with Metastatic Breast Cancer," Clinical Cancer Research, DC Vol. 5, pp. 1642-1649 (1999) Goss, "Preliminary Data from Ongoing Adjuvant Aromatase Inhibitor Trials," Clinical Cancer DD Research, Vol. 7, pp. 4397S-4401S (2001) Hill et al., "Aromatase inhibitors in breast cancer: Current and evolving roles," Current Drug Therapy, Vol. 69, No. 7 pp. 561-567 (2002) DE Goss, "Anti-Aromatase Agents in the Treatment and Prevention of Breast Cancer" Cancer Control, H. Lee Moffitt Cancer Center and Research Institute, Vol. 9, No. 2 (Suppl.), pp. 2-8 (2002) DF Goss et al., "Letrozole for the management of breast cancer," Expert Review of Anticancer therapy, "Vol. 2, No. 3, pp. 249-260 (2002) DG DH DI DJ DK DL DM DN

DATE CONSIDERED

^{*}EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.